

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Patrick J. Sweeney

Title: SPINAL DISC PROSTHESIS SYSTEM

Appl. No.: 10/619,757

Filing Date: 07/15/2003

Examiner: Philogene, Pedro

Art Unit: 3733

Conf. No.: 7389

DECLARATION UNDER 37 C.F.R. §1.131

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

I, Patrick J. Sweeney, state and declare that:

1. I am the inventor of all of the claims of the above-referenced patent application.
2. Prior to May 9, 2003, I conceived in the United States the invention described and claimed in at least claims 1-3, 8-16 and 27-41 of the above-referenced application.
3. Prior to May 9, 2003, I provided instructions to my patent figure draftsman to produce drawings of various embodiments of the invention claimed in the above-referenced patent application.
4. Prior to May 9, 2003, I received at least three facsimiles each including a set of draft figures produced by the draftsman in accordance with my instructions.

5. Copies of the three facsimiles including each of the draft figure sets are attached hereto as Exhibit A. Portions of the facsimiles have been redacted, including the send date of each facsimile. The send date of each facsimile is prior to May 9, 2003.

6. The drawings of Exhibit A provide evidence of the conception of the invention claimed in the above-referenced application, and specifically the invention of claims 1-3, 8-16 and 27-41.

7. On May 13, 2003, I provided an invention disclosure to my law firm. The invention disclosure and related correspondence forwarding the scanned invention disclosure are attached as Exhibit B.

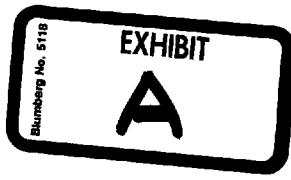
8. On June 24, 2003, Michelle Manning sent a draft of the above-referenced patent application to me as indicated in the related correspondence attached as Exhibit C.

9. On July 15, 2003 the above-referenced patent application was filed with the United States Patent and Trademark Office.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Date 1/22/09

By Patrick J. Sweeney



Pat,

hi! Please see Ed's
letter + work attached.

lme,
-e

Hi Uncle Pat,

I sketched up what you talked about in Northbrook the second day. The following questions are numbered as they are written on the 4 sketches I am having my mother fax to you right now. If you would rather call me to answer the questions rather than alter the images or write down your answers for the following questions, you can reach me at home or on my cell

Your answers are crucial to how the final renderings will appear. I will most likely have my mother fax the subsequent sketches before I do the final renderings. Some of these questions may seem redundant, but I just want to make sure I have down exactly what you would like to appear.

Here are the questions:

1.) Will more space be needed where the ends of the plates holding the cruciate spring and plastic bubble come close to each other? (look at side cross-section)

2.) Should the four side plates that will be screwed in be moved where I have placed the arrows on the sketch? (look at top and bottom cross sections)

3.) Will the inner plates holding the cruciate spring and plastic bubble have movement along the concave plates above the surface of the bone?

4.) The edges of the outer plates may need to be changed due to how they will impact each other. How should this be done? (I have some ideas, but I figure sharp edges are not a good idea.)

5.) Should the inner plates holding the cruciate spring and plastic bubble be shrunken down somewhat in order to provide the four side plates to have larger pegs to increase their rigidity?

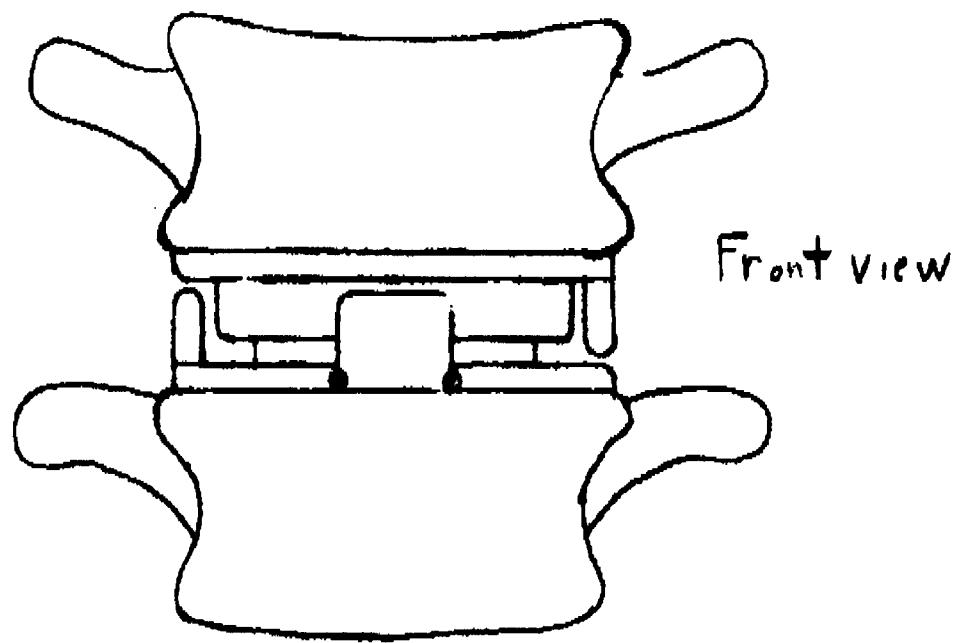
6.) Is the plastic bubble needed?

7.) How would you like the bone morphogenetic protein connections between the vertebra and the two permanent plates to be shown?

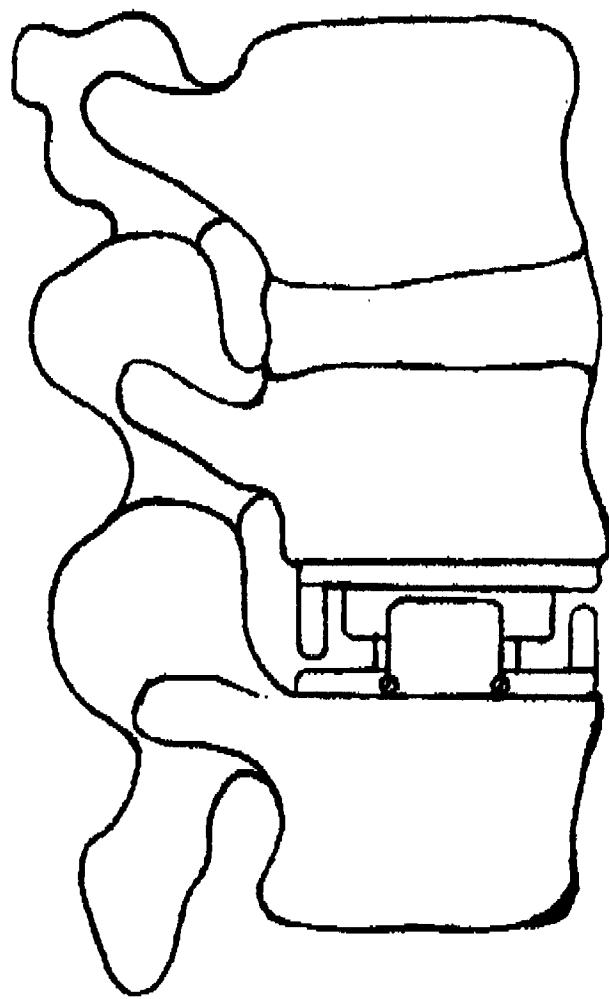
Right now I have shown an area being drilled out of the bone and a rough spike going into the bone so that the bone protein can grow into the crevices to create permanent rigidity as we talked about. Will the bone be drilled into in order to make the connection?

Will any support be provided by the outer plates coming into contact with each other? Should they ever come into contact? If so, should there be a soft layer on top of the plate edges?

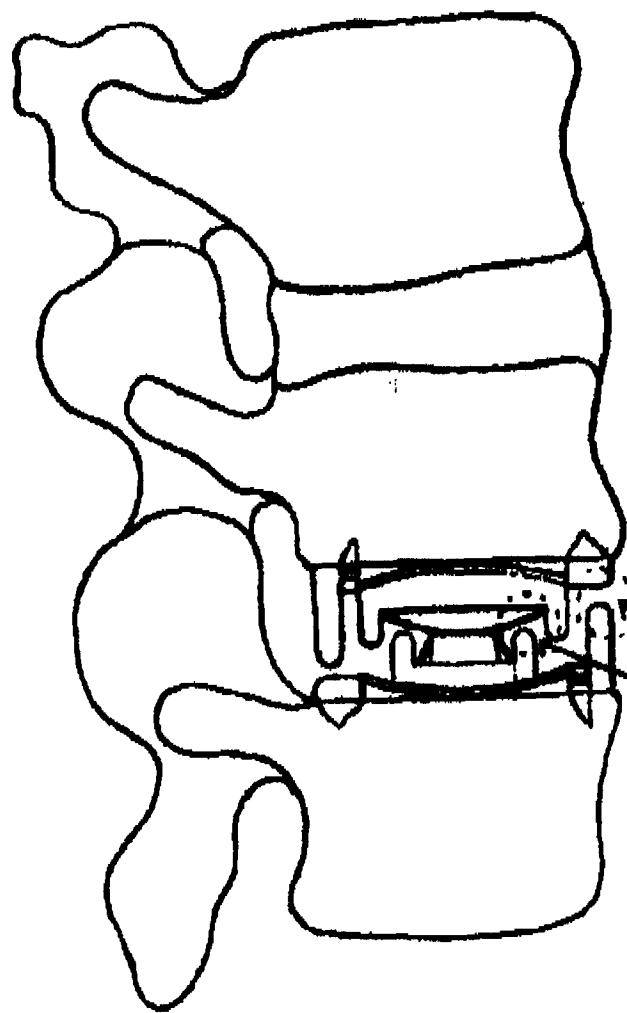
That's about it. I am really enjoying doing these sketches. There are plenty more to do including the finished renderings. Just fax this back to my mom asap, and I will get it back tonight. Thanks.
-Ed



Front view



Side view

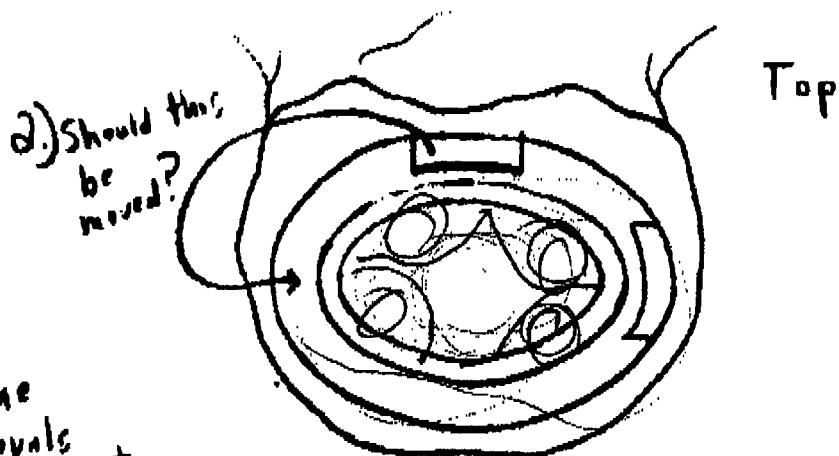


Cross Section

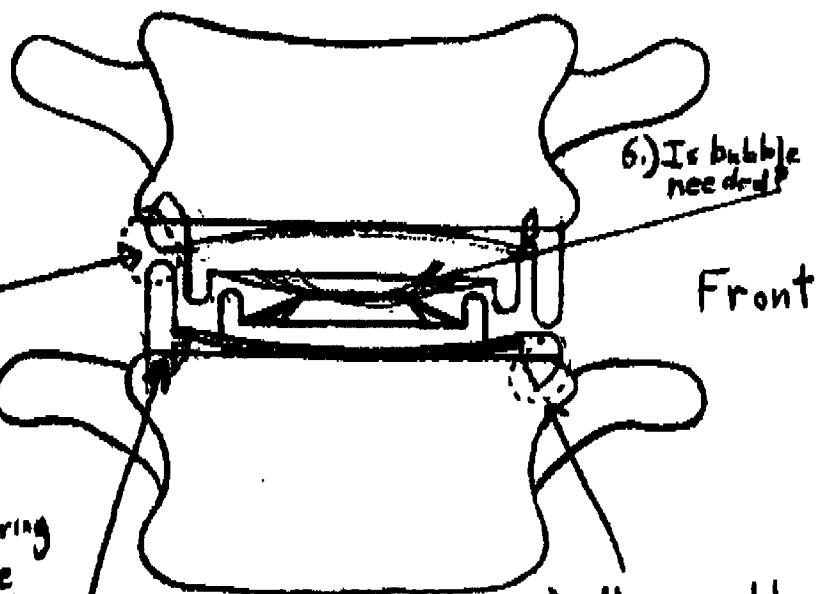
Side

1.) Will more space
be needed
at these
places?

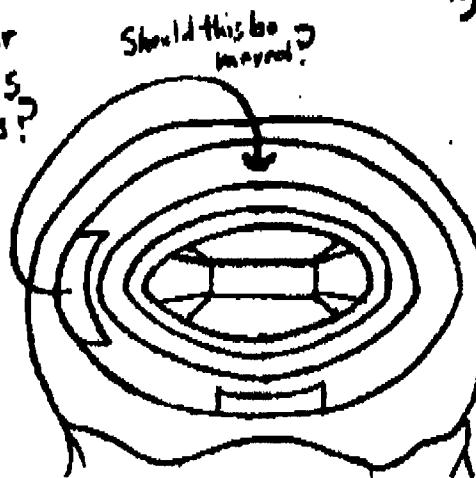
Cross Sections



3.) Will the inner ovals have movement along the concave plates above the bone surface?



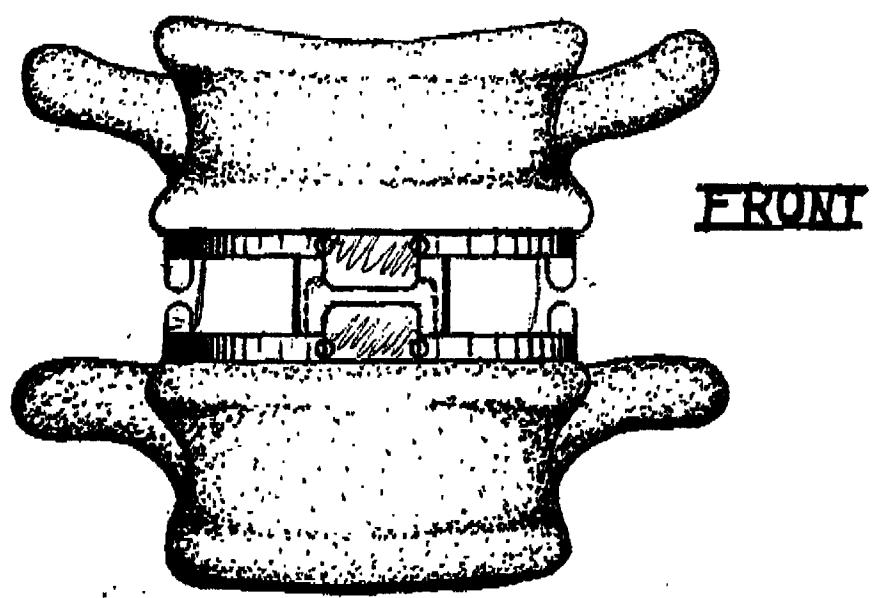
5.) Should the inner ovals (with cruciate spring and bubble) be pushed in further to enable the four detachable pieces to have larger pegs?

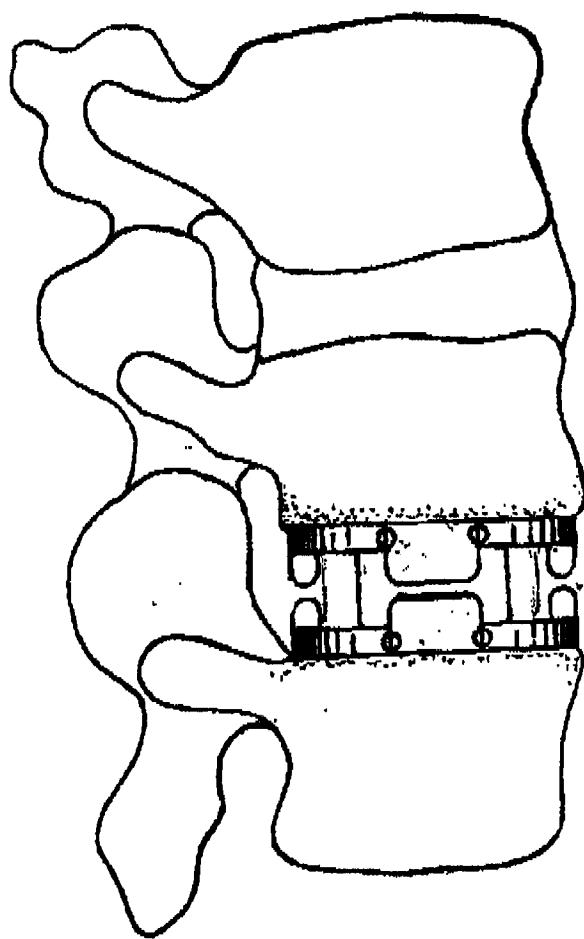


7.) How would you like the bone morphogenetic protein connections to the permanent plates to be shown?

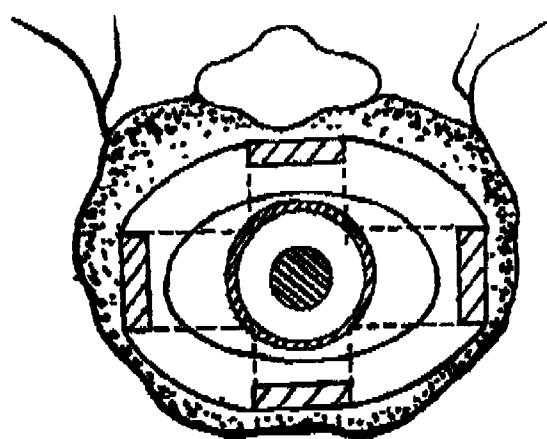
Will the vertebrae be drilled into in order to make the connection?

Bottom



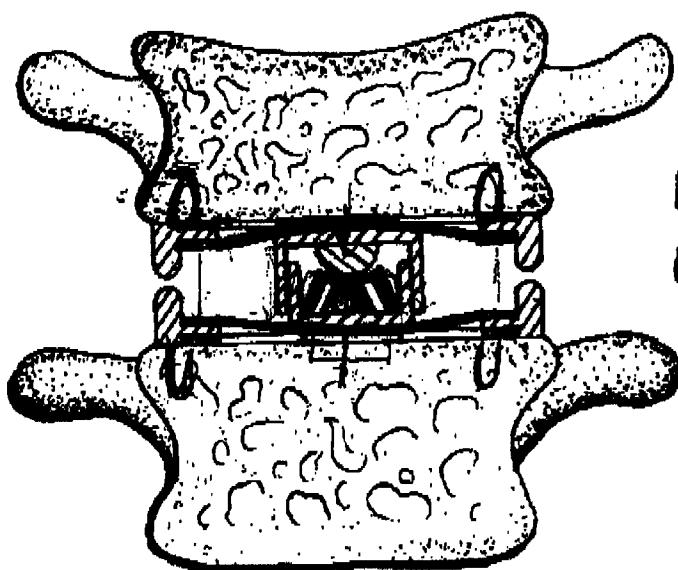


SIDE



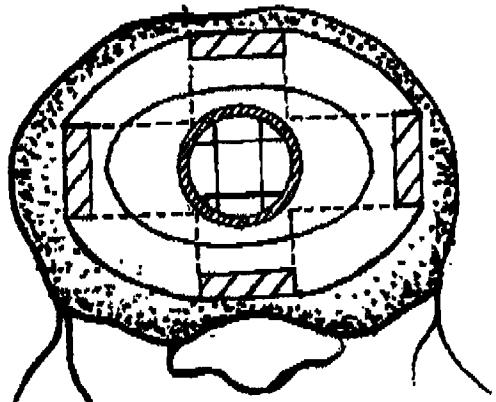
TOP

Cross-section



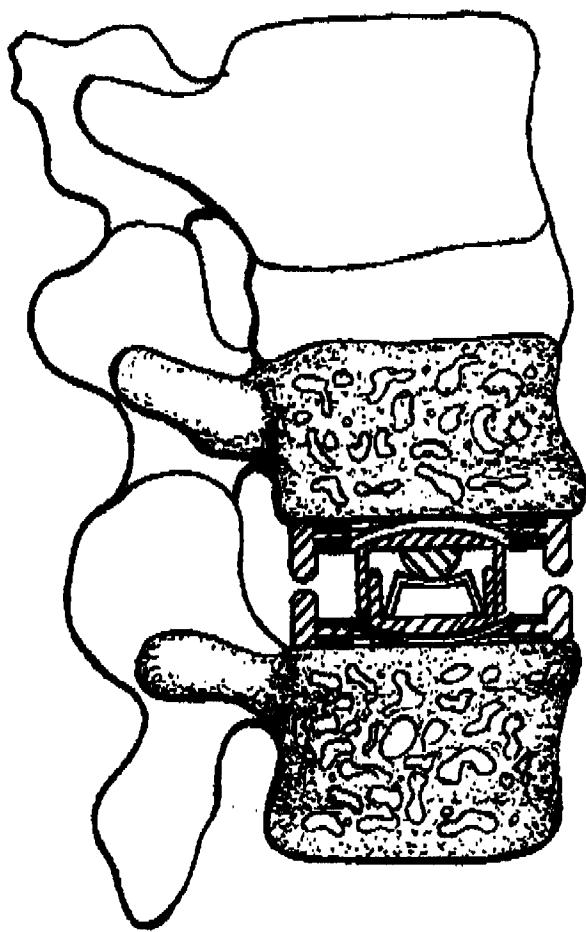
FRONT

Cross-section



BOTTOM

Cross-section



SIDE
CROSS-SECTION

Hi Ed,

If you could expand the size of the disc prosthesis out to the bumpers, put in the fixation pegs on the ring, and put the cross-shaped peg on the plate (4mm depth) that would be great. If you have time, I'd like to make the upper cup a little shorter, with around 2mm slack between it and the smaller cup too. Those are 2 separate thoughts. Thanks, Pat

Hi Uncle Pat,

I worked with this side cross-section alone to get some clarification before finishing these and working on your other ideas. I have all of the separate sketches you would like me to get done on a list. They will all be done after the weekend once I have clarified a couple things. My weekend is completely open, so keep your ideas flowing.

I was not sure what you meant by bumpers, so I expanded the rings of the disc prosthesis to the bumpers of the bone. Let me know if you meant otherwise. Perhaps you meant extend the larger cup to the inner bumpers of the rings. If so, did you want the shape of the cups to remain circle or be oval?

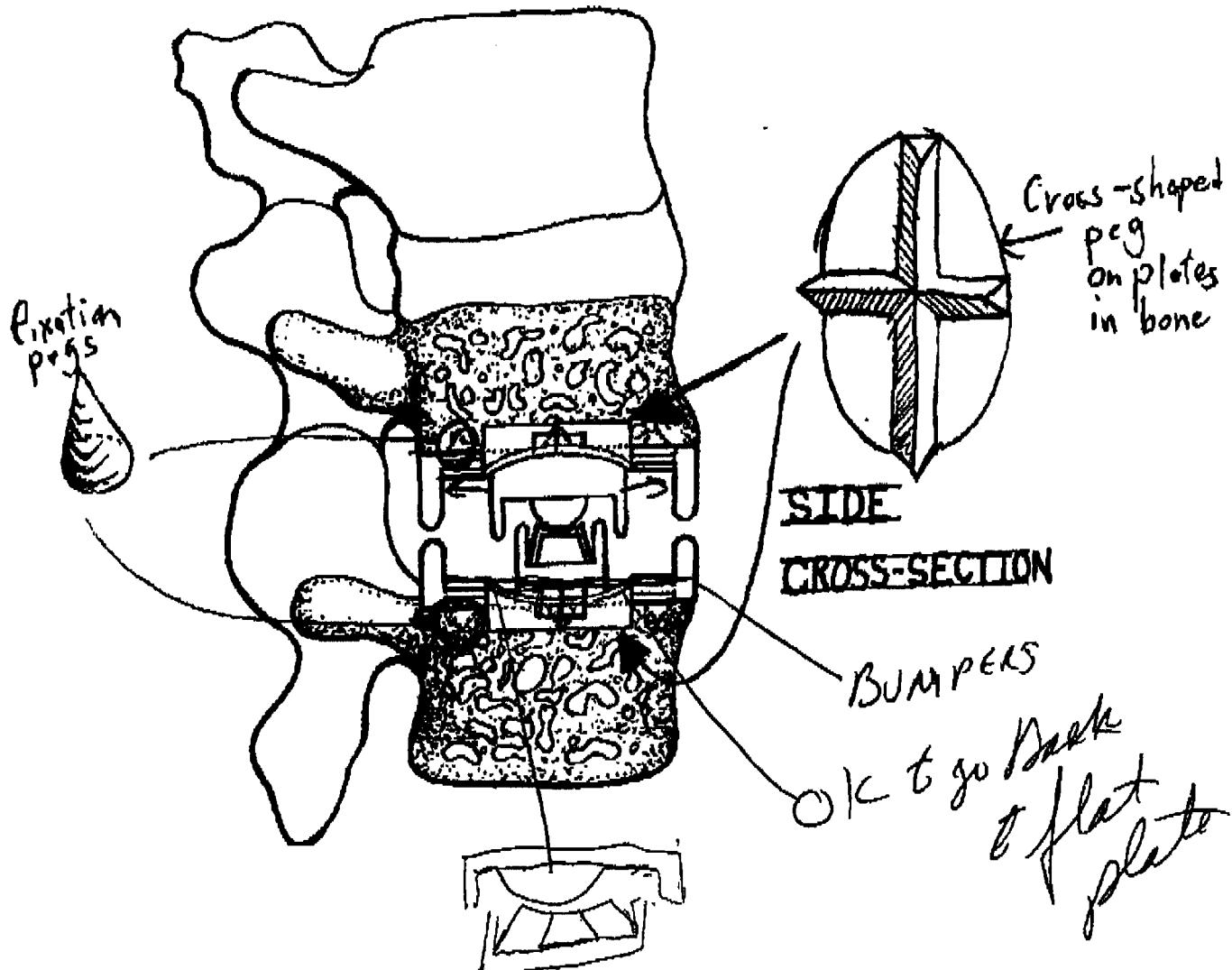
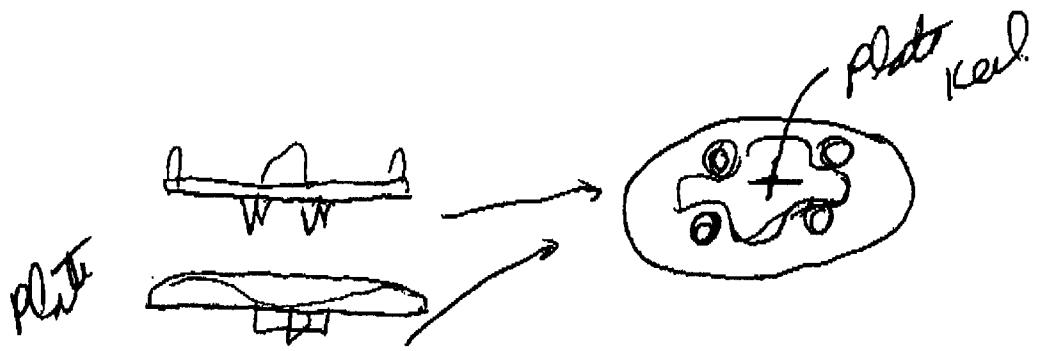
The cross-section depicts (roughly) the cross-shaped peg extending its four arms out to the edges of the ring. The peg fixes into the bone with a triangular cut on all arms of the peg digging 4mm in depth into the bone (shown with the dotted lines on the top and the bottom).

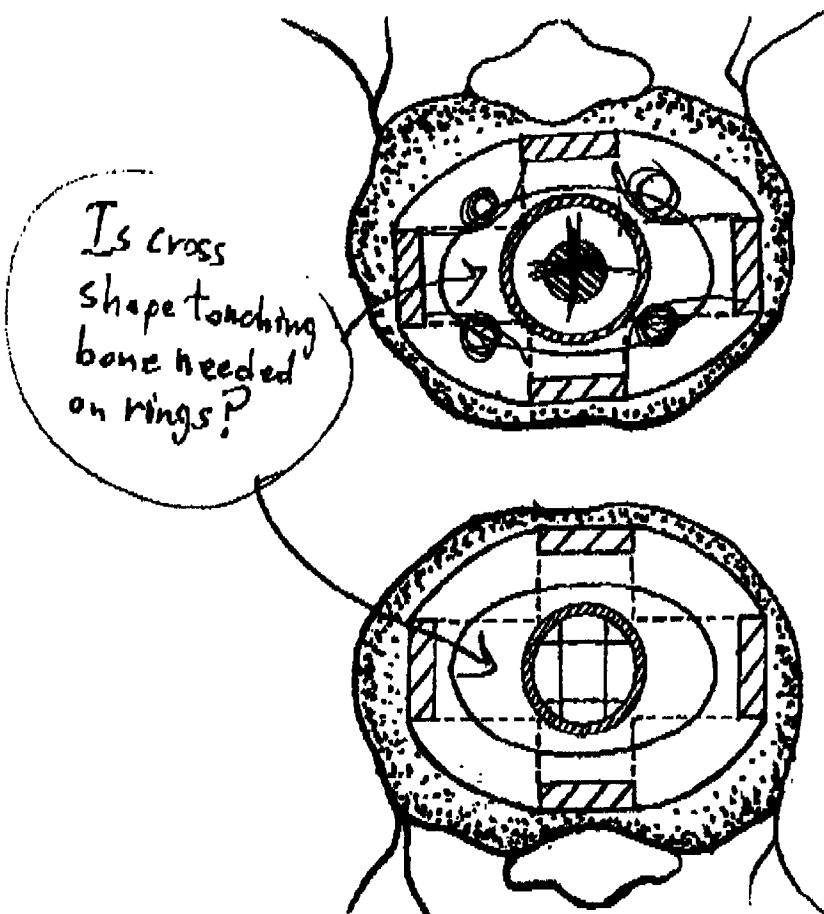
sketch required
If a peg is being used (such as the one discussed above), then would the cross shape on the bottoms of each ring sitting on the surface of the bones be needed? (Please refer to the top and bottom cross-sections of the second page of the faxed images) What purpose does that cross shape serve? Is it more surface area for fixation pegs?

4 Lastly, how many fixation pegs would you like on the rings into the bones? I have them now at about 3 - 4mm in depth and 4mm in diameter. They are cone-shaped, pointing into the bone. Will this work? Should I use the surface area mentioned in the last paragraph to include more fixation pegs?

like the concept
Much more is to come. I just need your comments on this. I would like to get going on some three-dimensional drawings once we get concerns kinked out. I will be home around 7:00 PM my time, 9:00 PM your time. We can discuss these then. I have a field trip with my sixth grade today until 5:30 PM. Thanks.

Ed





TOP

Cross-section

BOTTOM

Cross-section

Gundersen, Jeffrey S.

From: Manning, Michelle
Sent: Wednesday, August 30, 2006 2:31 PM
To: Gundersen, Jeffrey S.
Subject: FW: Invention disclosure from Dr. Patrick Sweeney



-----Original Message-----

From: Houston, Michael R.
Sent: Tuesday, May 27, 2003 9:13 PM
To: Manning, Michelle
Subject: FW: Invention disclosure from Dr. Patrick Sweeney

Here are the disclosures from Dr. Sweeney. The third one is the one I printed out on fenestrated screws. The first two regard discs.

Mike

-----Original Message-----

From: Kassel, Mark A.
Sent: Tuesday, May 20, 2003 11:48 AM
To: Houston, Michael R.
Subject: FW: Invention disclosure from Dr. Patrick Sweeney

Mark A. Kassel
Foley & Lardner
150 E. Gilman Street
Madison, Wisconsin 53701
Ph. 608.258.4272
Fax 608.258.4258

The information transmitted is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from any computer.

-----Original Message-----

From: Martin, Matthew E.
Sent: Tuesday, May 13, 2003 5:30 PM
To: Kassel, Mark A.

Cc: Green, Edward
Subject: Invention disclosure from Dr. Patrick Sweeney

Mark,

Here are the scanned documents from this morning's meeting. I will mail you photocopies as well.

Matt

Confidential

This document and the concepts discussed within are the sole property of Patrick J Sweeney MD

SUMMARY OF INVENTION

An artificial disc prosthetic replacement system is described. Placed via anterior, anterolateral or lateral approach, it may be revised multiple times from multiple approaches. This will be useful as the disc replacement elements wear out or are technologically outmoded. This system will allow interchangeability of multiple disc technologies for revision purposes. It will also allow conversion to an interbody fusion without removal of the entire system.

A scaffolding system is the basis of fixation that will, in general, rest on the periphery of the vertebral endplate. While a scaffold covering the entire endplate, or portions of it, is also conceived, preserving the central endplate will allow revision fusion. This scaffold will initially be cobalt chrome, but titanium, plastic, ceramics, and other composites will be tested. This scaffold will anchor to the superior and inferior endplates via pegs, spikes or screws and may have a coating to assist with bony ingrowth. Future attachment to a vertebral prosthesis is possible.

Cutouts or anchoring points will be positioned around the scaffold allowing firm fixation of various replaceable disc components. Other anchoring points will be positioned to allow for removable buttresses that may serve as extension or lateral bending or flexion constraints. These may also serve as retention devices for disc replacements that are not rigidly attached to the vertebrate or the scaffold. These buttresses may have variable sizing to vary the degree of constraint in one or more directions.

Disc replacement technologies that are compatible comprise mechanical, hydraulic, gas or fluid filled, elastomeric, and functionally similar discs. These may be rigidly fixed to the scaffold or rest on high friction plates or be placed in a mobile fashion on low friction plates affixed to the scaffolds, such as polished metal or ceramic.

An initial disc replacement model will involve high friction metallic plates rigidly fixed to the superior and inferior scaffolds in a removable manner. Extension and lateral flexion blocks will be attached to the scaffold. These blocks will initially be metallic, also serving to contain the removable disc element. One three-component prostheses is described that will rest between the high friction plates. A larger cylindrical cup will contain a reciprocally positioned smaller cup. The relative size of these cups may vary to control the degree of global constraint. The cups will initially be metallic with high friction outer surfaces while other materials including ceramic will follow. The high friction surfaces will allow the prosthesis to rest securely within the constraints of the outer structure. Alternatively, a prosthesis with a low friction outer surface could be positioned on low friction outer plates in a manner that would permit movement between the plates and prosthesis while still being easily revised. The larger outer cup would have a convex internal surface that will articulate with a load bearing, force absorbing construct resting in the smaller cup. This load bearing construct will have a concave surface to complement the opposing internal surface. This relationship may be reversed. The load bearing construct may be metallic and be positioned inside the smaller cup in a

Confidential

This document and the concepts discussed within are the sole property of Patrick J Sweeney MD

stressed manner allowing it to function in a spring like fashion. The shape of this support will initially be cruciate but other shapes are envisioned. This support may also be elastomeric, or hydrogel resting snugly inside the smaller cup. The outer cups would also serve to contain wear debris that might otherwise stimulate an inflammatory response as often seen in deteriorating, peripheral joint replacements. A "nested" cup design may be used, providing flexibility in the axis-of-motion location. In this situation an internal cup would be integral to both of the opposing outer cups. This cup would contain the articulating elements and be positioned away from the center of the larger cups, thus allowing for compensation of any difficulties with scaffold placement and proper location of the axis-of motion.

This system may also be useful in performing primary interbody fusions that may later be converted to arthroplasty if a primary arthroplasty is not possible. The fusion could be removed anteriorly or laterally and replaced with a disc prosthesis while keeping the scaffold in place. A special insert formed to bear the stresses of the interspace containing osteoconductive as well as osteoinductive material would rest in the scaffold allowing bone growth across a defined area. This would be easily disrupted at the time of arthroplasty allowing removal of the insert and replacement with the prosthesis.

Other objects and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings. Throughout the drawings, like reference numerals refer to like parts.

BRIEF DESCRIPTION OF THE DRAWINGS

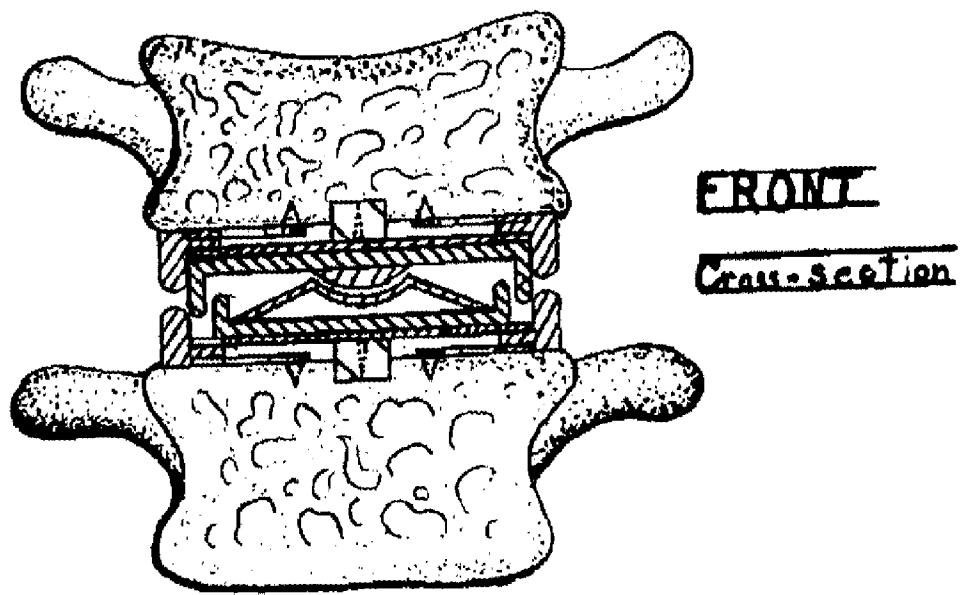
FIG. 1 is a

DETAILED DESCRIPTION

While the invention will be described in connection with a preferred embodiment and procedure, it will be understood that it is not intended to limit the invention to this embodiment or procedure. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

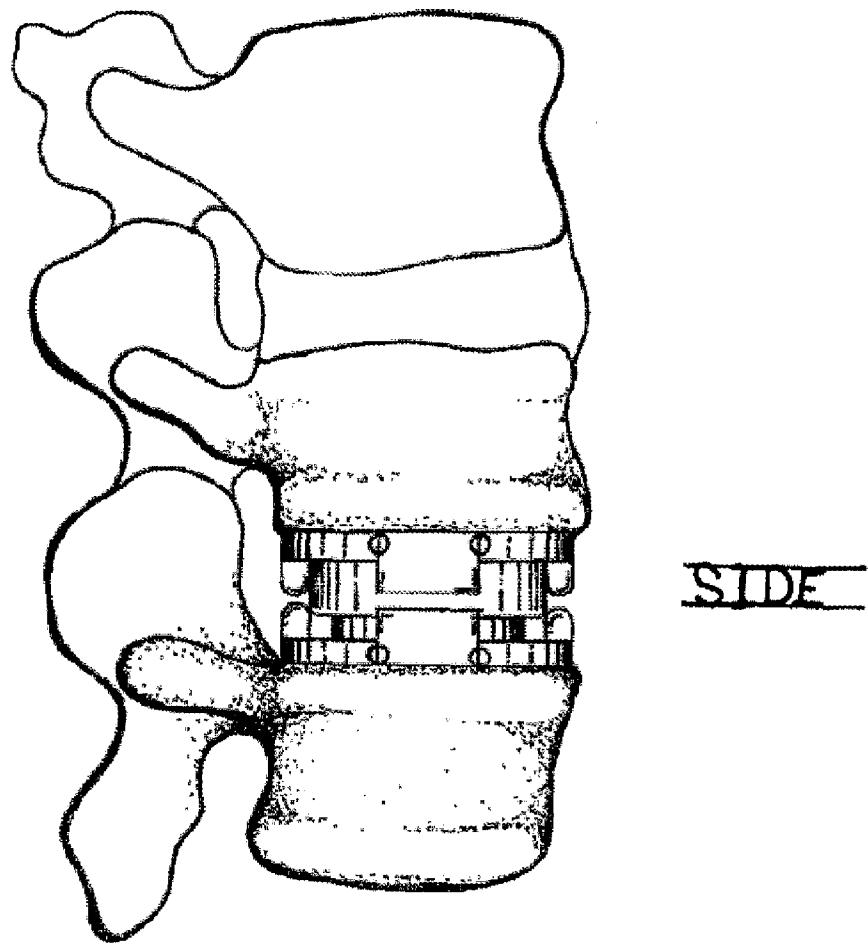
Confidential

**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**



Confidential

**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**



Confidential

**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**

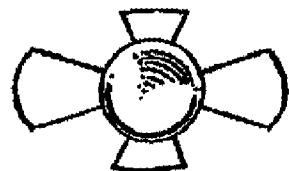


Confidential

**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**

SPRING

TOP



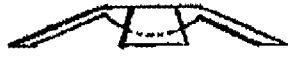
CROSS-SECTION



FRONT



SIDE

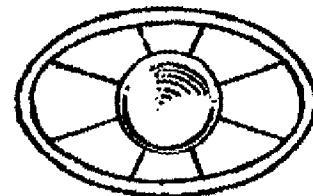


Confidential

**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**

BOTTOM

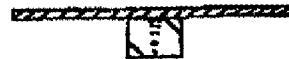
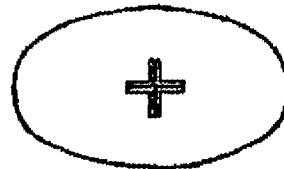
CUP



Confidential

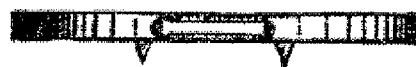
**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**

PLATE
TOP + BOTTOM
ARE THE SAME



Confidential

This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD



FRONT

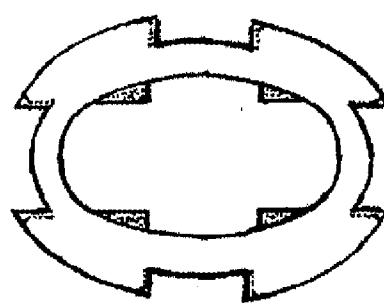
RING



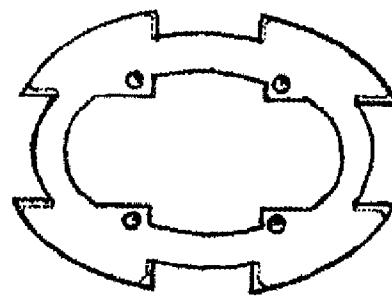
CROSS-SECTIONS

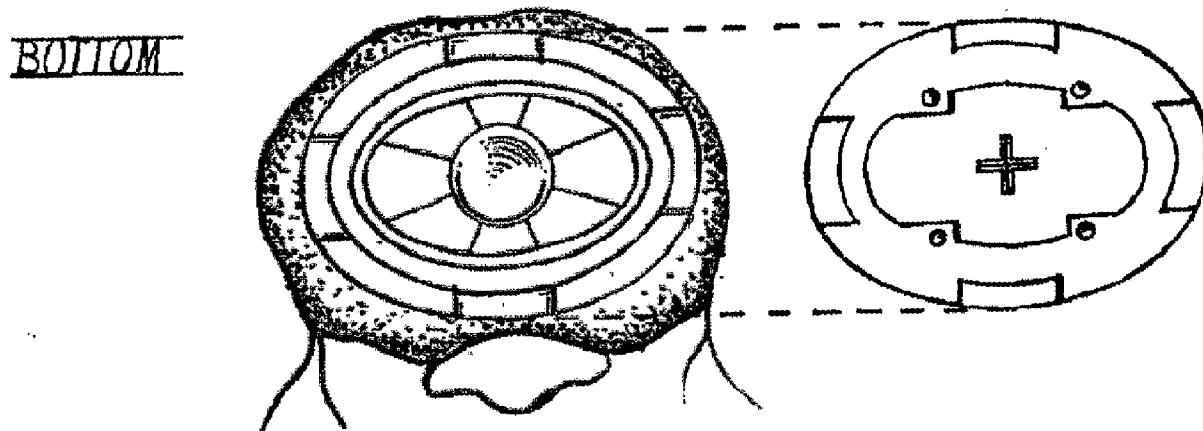
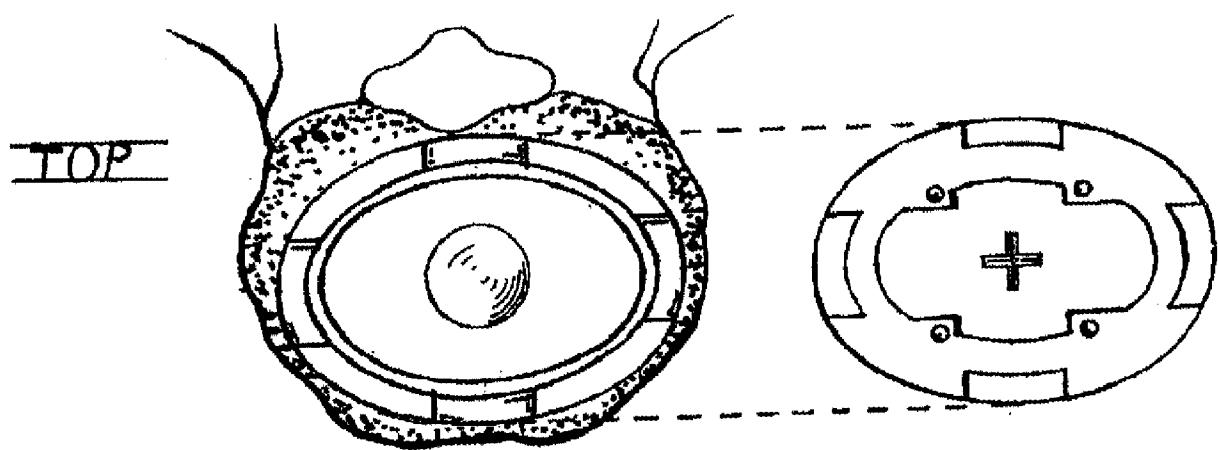
SIDE

TOP



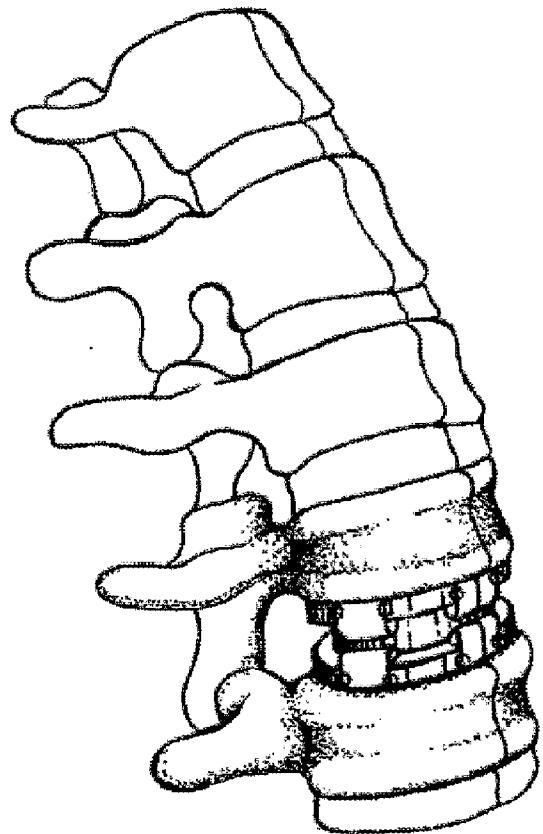
BOTTOM





Confidential

This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD



Confidential

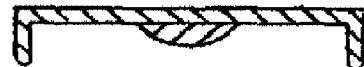
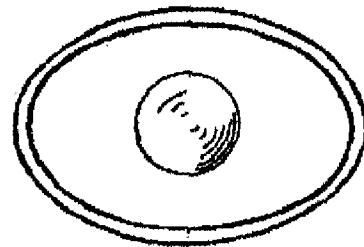
**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**

Confidential

**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**

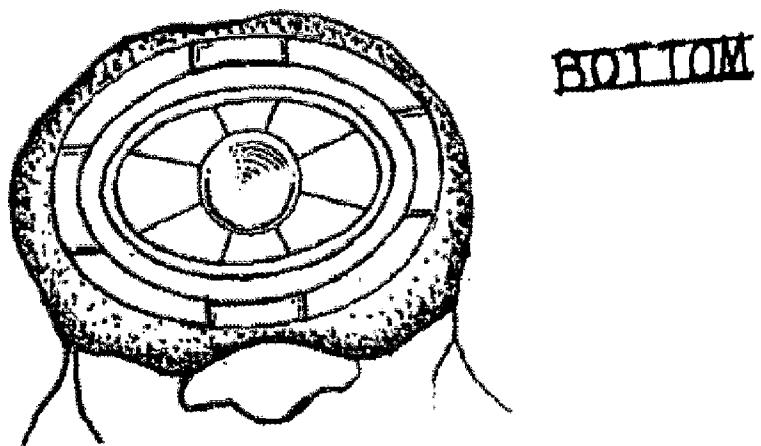
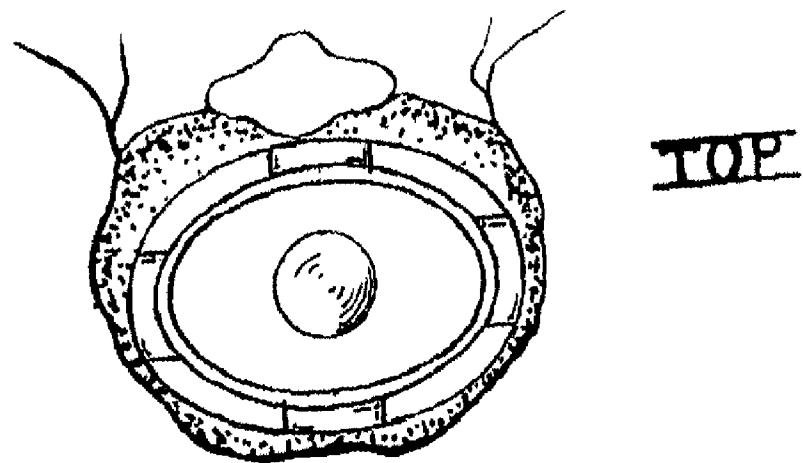
TOP

CUP



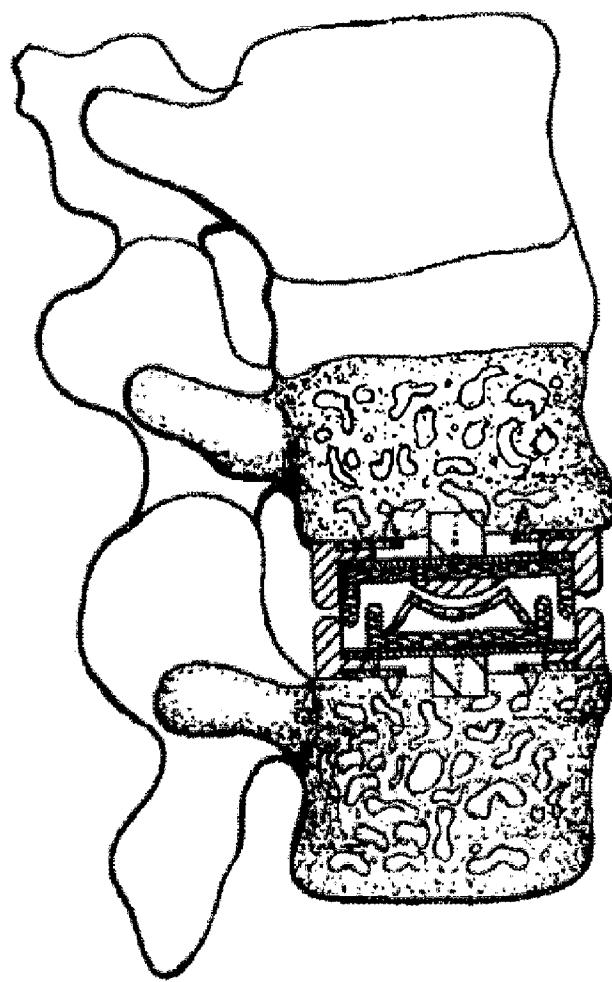
Confidential

**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**



Confidential

**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**

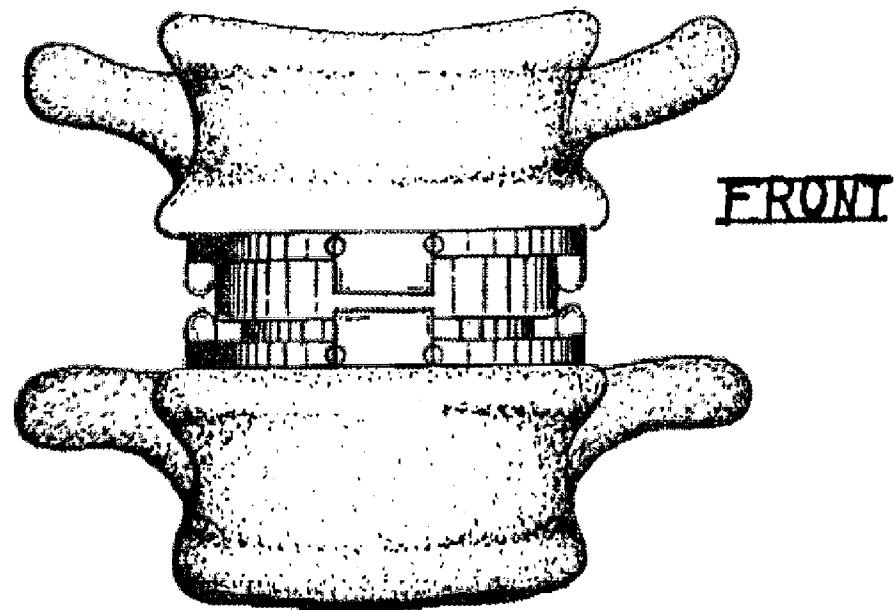


SIDE

CROSS-SECTION

Confidential

**This document and the concepts discussed within are the sole property
of Patrick J Sweeney MD**



From: Manning, Michelle
Sent: Tuesday, June 24, 2003 9:41 PM
To: 'PJPSweeney@aol.com'
Cc: Green, Edward; Martin, Matthew E.; Kassel, Mark A.; Bohman, Monica J.
Subject: Patent Application for Prosthetic Disc System (Our ref. 029815-0101)

Dear Dr. Sweeney,

Attached please find a draft of the above-referenced patent application. You will notice that I have largely re-drafted the claims. I believe the new claims are both broader and more clear than the original set. I still have several remaining questions which are highlighted throughout the text. The figures referred to in the application correspond to the figures you faxed to us. However, the parts have been renumbered. I will fax copies of the figures with the revised figure and part numbers for your convenience tomorrow. These figures will be rough. Eventually, we will have to prepare cleaner figures.

I would like to speak with you regarding this application. In particular, I would like to go over some of the definitions with you and discuss some prior art devices. I will email several patents to you tomorrow. It would be helpful if you could review these patents so we can discuss them. I will be out of the office tomorrow (Wednesday) and Friday. Please let me know your availability early next week so I can set up a conference call. I will likely add more claims to the application after we have spoken.

As always, if you have any immediate questions or concerns with regard to this matter please do not hesitate to contact me.

Michelle Manning
Foley & Lardner
150 E. Gilman Street
Madison, WI 53701
Phone: (608) 258-4305
Fax: (608) 258-4258

The information transmitted is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, retransmission, dissemination or other use of, or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you received this in error, please contact the sender and delete the material from any computer.



MADI_432470_1.DOC